

Narendrakumar Patel
Deposition October 20, 2009

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Q. Did you have any knowledge
16 of any lab analyst who did not accurately
17 write the information in the lab notebook
18 from the TotalChrom or TurboChrom
19 printout?
20 MR. ANDERTON: Objection.
21 I'm going to ask that you phrase
22 your question relating
23 specifically to digoxin.

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MR. ANDERTON: I'm going to
11 ask you to listen to the question
12 and I'm going to instruct you to
13 answer only with respect to
14 digoxin.
15 THE WITNESS: Okay.
16 BY MR. MILLER:
17 Q. Are you aware for any
18 product that was being produced by
19 Actavis, of lab analysts not accurately
20 writing in a lab notebook what's
21 reflected on the results from TotalChrom
22 or TurboChrom?
23 MR. ANDERTON: Again, I'm
24 going to object and you may answer
1 the question, but only as concerns
2 knowledge about digoxin.

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9 Q. Next sentence: "Instances
10 were found where analysts aborted and
11 failed to complete chromatographic
12 testing runs after an out-of-specification
13 test result was obtained."
14 On digoxin or any product at
15 Actavis, were you aware this was taking
16 place?
17 MR. ANDERTON: Objection.
18 You may answer the question but
19 only with respect to digoxin.

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Q. I'm going to read paragraph
6 3, sir, if you're there. "There was a
7 failure to check for accuracy the inputs
8 to and outputs from the 'Total Chrom Data
9 Acquisition System,' which is used to run
10 your firm's HPLC instruments during
11 analysis of drug products."
12 Are you aware of this
13 happening for digoxin or any product at
14 Actavis Totowa?
15 MR. ANDERTON: Objection.
16 I'm going to instruct you to
17 answer the question only with
18 respect to digoxin.

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Q. Are you familiar with or
6 told of any lab technicians that did not
7 properly represent the data in a lab
8 notebook from the TotalChrom or
9 TurboChrom printout regarding assay for
10 blend tests?
11 MR. ANDERTON: Objection.
12 You may answer that question
13 only -- I instruct you to answer
14 that question only with respect to
15 digoxin.

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Q. Are you aware of digoxin or
16 any other product where a lab analyst has
17 not accurately written the findings in
18 the notebook for a digoxin stability test
19 from the printout of TotalChrom or
20 TurboChrom?
21 MR. ANDERTON: Objection.
22 I'm going to instruct you to
23 answer that question only with
24 respect to digoxin.

Eamonn Murphy
Deposition October 21, 2009

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9 Q. With regard to any of these
10 drugs, did you participate in drafting
11 validation protocols for these, for any
12 of these?
13 A. Yes.
14 Q. And which ones, if any?
15 MR. ANDERTON: Objection.
16 Fred, I think we're at that point
17 where we're outside the scope and
18 we're into the area contemplated
19 by PTO 27 where we're asking about
20 products other than Digitek. I've
21 let a little bit of it go, but at
22 this point, I'm going to instruct
23 the witness not to answer that
24 question.

Page 89/90

5 Q. Have you ever gotten any
6 written letter that was put in your
7 personnel file that outlined any failing
8 of either yourself or your quality
9 control group for any reason?
10 MR. ANDERTON: Objection.
11 I'm going to instruct the witness
12 to answer that only with respect
13 to yourself.
14 THE WITNESS: Can you ask me
15 the question again, please?
16 BY MR. THOMPSON:
17 Q. Have you ever gotten a
18 reprimand that was included in your
19 personnel file for any fault or problem
20 that you had at work or that your quality
21 control group had?

22 MR. ANDERTON: And, again,
23 I'm going to instruct you to
24 answer only with respect to
1 yourself.
2 THE WITNESS: With respect
3 to myself, no.
4 BY MR. THOMPSON:
5 Q. How about with respect to
6 the quality control group as a whole?
7 MR. ANDERTON: Objection.
8 I'm going to instruct the witness
9 not to answer.

Bakul Shah
Deposition October 23, 2009

Page 43-44
1 Q. Can you think off the top of
2 your head as you're sitting here the name
3 of any product that has a specific
4 product book?
5 MR. ANDERTON: Objection.
6 BY MR. MILLER:
7 Q. It's okay to answer.
8 MR. ANDERTON: It's not okay
9 to answer. I'm going to instruct
10 the witness not to answer except
11 in respect to digoxin.
12 MR. MILLER: I think when --
13 I disagree with that. I think I'm
14 entitled to how he conducted
15 business as a QC analyst. This is
16 not --
17 MR. ANDERTON: You're asking
18 about specific testing questions
19 now relating to specific --
20 specific practices relating to
21 specific products other than
22 digoxin. I'm letting the general
23 lab practice questions go.
24 MR. MILLER: Then this one
1 should go, this is a general lab
2 practice question.
3 MR. ANDERTON: About a
4 specific product.
5 MR. MILLER: He doesn't
6 recall which products this is done
7 or not. I'm asking for an example
8 to see how it's done. He doesn't
9 know if digoxin is done this way
10 or not. If you --
11 MR. ANDERTON: Well, you
12 didn't ask him about digoxin. If
13 you want to ask him about digoxin,
14 that's fine.
15 MR. MILLER: I did.
16 MR. ANDERTON: Okay. PTO 27
17 is clear about what non-digoxin
18 information can be -- is subject
19 to discovery and what isn't.

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3 Q. You're aware that product
4 production at Little Falls was halted in
5 August of 2008?
6 A. Yes.
7 Q. What's your understanding as
8 to why that took place?
9 MR. ANDERTON: Objection.
10 You're talking specifically about
11 Digitek?
12 MR. MILLER: No.
13 MR. ANDERTON: I'm going to
14 instruct the witness to answer
15 only with respect to Digitek if he
16 knows.

Kwame Adjei
October 26, 2009

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5 Q And what products are you testing
6 today for Actavis?
7 MR. ANDERTON: Objection. I
8 instruct the witness not to answer except
9 with respect to digoxin.

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4 Q As a lab analyst, have you ever made
5 an error accidentally or any other way when
6 transcribing data from a printout such as
7 Empower into your lab notebook?
8 MR. ANDERTON: Objection. I'm
9 going to instruct the witness to answer
10 only with respect to digoxin.

Page 90/91/92/93

9 Q Okay. Did you do any testing on
10 hydroxyzine?
11 MR. ANDERTON: Objection. I'm
12 going to instruct the witness not to
13 answer.
14 THE WITNESS: I don't remember.
15 MR. BLIZZARD: Let me just make
16 sure I'm clear on this. We're doing
17 discovery here. Are you-- and you're
18 instructing a witness not to answer a
19 question that I'm asking in the discovery
20 period of the case?
21 MR. ANDERTON: We have -- I'm
22 sure you're familiar, Ed, with PTO27,
23 which sets the scope of allowable
24 discovery in this case and limits
1 discovery to digoxin and digoxin-related
2 activities except with respect to
3 specific information laid out in PTO27.
4 MR. BLIZZARD: I'm not talking
5 about specific testing about another
6 product.
7 MR. ANDERTON: You asked --
8 MR. BLIZZARD: I'm asking him
9 about whether or not he's familiar with a
10 specific product. And this is background

11 information for the purposes of
12 discovery. And if you're going to
13 instruct him -- typically, the cases I'm
14 involved in, there's only instructions
15 not to answer when there's a privilege
16 issue. But you've been consistently
17 instructing witnesses not to answer on
18 discovery matters. From my
19 understanding, this is not in violation
20 of the current PTO, so that's why I'm
21 asking the question.

22 MR. ANDERTON: Well, first of
23 all, your question was not limited to
24 whether he had knowledge of a specific
1 product. You asked him, and the record
2 will show, expressly whether he tested
3 that product.

4 MR. BLIZZARD: Yes, I am.

5 MR. ANDERTON: That is --

6 MR. BLIZZARD: That was his
7 job.

8 MR. ANDERTON: That is a
9 direct -- that is directly outside the
10 scope of PTO27. The rule explicitly
11 permits instruction to a witness not to
12 answer to enforce the terms of a court
13 order. We have that order. It's PTO27.
14 It speaks to the non-Digitek information
15 that you can and can't inquire about in
16 this litigation. So we will continue to
17 instruct the witness not to answer when
18 you ask specific questions about specific
19 activities related to products other than
20 Digitek.

21 BY MR. BLIZZARD:

22 Q Okay. Did you work on hydroxyzine?

23 MR. ANDERTON: Objection. I'm
24 going to instruct the witness not to
1 answer.

2 BY MR. BLIZZARD:

3 Q Did you work on oxycodone?

4 MR. ANDERTON: Objection. I'm
5 going to instruct the witness not to
6 answer.

7 BY MR. BLIZZARD:

8 Q Did you work on phentermine?

9 MR. ANDERTON: Objection. I
10 instruct the witness not to answer.

11 BY MR. BLIZZARD:

12 Q Did you -- would you work on
13 glyburide?

14 MR. ANDERTON: Objection. I
15 instruct the witness not to answer.

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16 Q Was that rule the same for Digitek
17 as it was for other drugs?

18 MR. ANDERTON: Objection. I'm
19 going to instruct the witness to answer
20 only with respect to Digitek.

Page 123/124

20 Q If you look, do you see on
21 observation No. 1 here it says: "An NDA-Field
22 Alert Report was not submitted within three
23 working days of receipt of information
24 concerning a failure of one or more
1 distributed batches of a drug to meet the
2 specifications established for it in the
3 application."
4 Do you see that?
5 A Yes.
6 Q Were you ever made aware of that
7 failure?
8 MR. ANDERTON: Objection. I'm
9 going to instruct the witness not to
10 answer. This information relates not to
11 Digitek.

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2 Q Was it ever brought to your
3 attention that it wasn't followed from time to
4 time by people who were working in the lab?
5 MR. ANDERTON: Objection. I
6 instruct the witness to answer only with
7 respect to Digitek.

Anil Patel
October 27, 2009

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1 What pills have you worked on for
2 Actavis doing testing?
3 MR. ANDERTON: Objection.
4 I instruct the witness to
5 answer only with respect to digoxin.
6 MR. BLIZZARD: Okay. So he's
7 told me he doesn't remember whether he
8 worked on Digitek after telling me he
9 didn't work on Digitek. And now when I
10 ask what he is working on, I'm being told
11 that you're instructing him not to
12 answer. Is that right?
13 MR. ANDERTON: If you'd perhaps
14 use a different term you, you might...
15 MR. BLIZZARD: Well, I'm asking
16 really what your instruction is because
17 I'm not --
18 MR. ANDERTON: My instruction
19 is that he should testify -- that I'm not
20 going to allow him to testify about
21 specific product testing he did on
22 products other than digoxin.

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8 Q Did you ever become aware that the
9 good manufacturing procedures in the lab at
10 Little Falls were being routinely violated?
11 MR. ANDERTON: Objection.
12 You may answer.
13 And I instruct the witness to
14 answer only with respect to Digitek, or
15 digoxin. Sorry.
16 THE WITNESS: No.

Page 92/93

10 Q Can you give me a sense for your
11 time as you've been employed, from 1999 until
12 today, how often do out-of-specification
13 results occur?

14 MR. ANDERTON: Objection.

15 I'm going to instruct the
16 witness to answer only with respect to
17 digoxin.

18 MR. MILLER: I'm not asking for
19 any individual product here. I'm asking
20 for the -- I don't want to know product
21 names. I'm just looking for how often an
22 out-of-specification result occurs for a
23 lab analyst at the quality control
24 department.

1 MR. ANDERTON: I understand.

2 My objection stands and my instruction
3 stands.

4 Please answer that question

5 only with respect to digoxin.

Paul Galea

December 9, 2009

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11 Q. Did GMP issues ultimately
12 result in the shutdown of production of
13 all products in August 2008 at Actavis
14 Totowa?

15 MR. ANDERTON: Objection.

16 You may answer.

17 Actually, wait. I instruct you to
18 answer only with respect to Digitek.

19 THE WITNESS: With respect to

20 Digitek, yes.

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17 Q. And that observation, as
18 described there, would that be a violation
19 of good manufacturing practices?

20 MR. ANDERTON: Objection.

21 And I'm going to enter a kind of a
22 global objection to -- so that I'm not going to
23 have to raise it every time to all of these
24 inquiries regarding any issue on any of these

1 FDA documents that relates to a product other
2 than Digitek, just so that it's in the record.

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2 Q. And there was a voluntary
3 commitment to perform product assessments
4 and to requalify equipment, evaluate it
5 and, as needed, remediate and requalify
6 methods and perform new process and
7 cleaning validation studies prior to the
8 reintroduction of any product to the
9 market?

10 Do you see that?

11 A. Yes.

12 Q. On the last item, has that been
13 accomplished?

14 MR. ANDERTON: Objection.

15 I'm going to instruct you to answer
16 only with respect to Digitek.
17 THE WITNESS: Digitek has not been
18 reintroduced.

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20 Has anybody communicated to you
21 about why they shut down the plant and recalled
22 all the products made at the plant?

23 MR. ANDERTON: Objection.

24 I'm going to instruct the witness
1 to answer only with respect to Digitek.

2 THE WITNESS: With respect to
3 Digitek, it was in view of the findings that the
4 FDA found.

5 BY MR. BLIZZARD:

6 Q. Well, they suspended operations at the
7 entire plant, didn't they?

8 A. Yes.

9 Q. Do you know why?

10 MR. ANDERTON: Objection.

11 THE WITNESS: I believe they wanted
12 to ensure that they could address the findings
13 from the FDA before resuming any manufacturing.

21 Q. Okay. Because of the findings
22 of the FDA, and the involvement in -- of
23 senior management in the discussion with
24 FDA, was it uncertain whether the drugs
1 being produced by the plant, any of them,
2 were in compliance with GMPs?

3 MR. ANDERTON: Objection.

4 I instruct the witness to answer
5 only with respect to Digitek.

6 THE WITNESS: I do not know if --
7 if there was a -- if they were uncertain or
8 not. I did not make that decision.